REMARKS

Claims 1-14, 16-18 and 20-59 will be pending upon entry of this Response to Notice of Non-Compliant Amendment. Claims 31-59 have been withdrawn as directed to a non-elected invention. Applicants reserve the right to file divisional applications directed to the non-elected claims.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-14, 16-18, and 20-30 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437), further in view of Bartels (U.S. Application No. 2003/0157195).

Claim 1 is directed to a tissue product comprising a tissue paper and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent, from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, and an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed

extract, green tea extract, rosmaric acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof. No more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Klofta, et al. disclose an anhydrous lotion composition for killing viruses and bacteria in addition to imparting a soft, lubricious, lotion-like feel when applied to tissue paper. The lotion composition comprises at least one antimicrobial selected from an antiviral, antibacterial, and mixtures thereof; at least one hydrophilic solvent; at least one skin conditioning agent; and at least one hydrophilic surfactant. When used in the lotion formulation, the antiviral is present in the lotion composition in an amount of from about 1% (by weight) to about 60% (by weight) and the antibacterial is present in an amount of from about 0.1% (by weight) to about 6% (by weight). Hydrophilic solvents can include glycol type solvents such as polyethylene glycols, glycerin, ethylene glycol, propylene glycol, polypropylene glycol, ethanol, isopropanol, hexylene glycol, and mixtures thereof and are present in the lotion composition in an amount of from about 5% (by weight) to about 60% (by weight).[1] Hydrophilic surfactants such as ethoxylated alcohols are present in the lotion formulation in an amount of from about 0.1% (by weight) to about 60% (by weight). Skin

[1] U.S. 6,238,682 at column 17, lines 41-42.

conditioning agents include petroleum-based agents such as mineral oil and petrolatum; fatty acid ester type agents, fatty alcohol type agents, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures thereof and are present in the lotion composition in an amount of from about 0.1% (by weight) to about 60% (by weight).[2] Typically, the skin conditioning agents have either a plastic or fluid consistency at 20°C (i.e., ambient temperatures).[3] As the skin conditioning agents have a plastic or fluid consistency at 20°C, they tend to flow or migrate on the surface of the tissue product.[4] The lotion composition can further optionally include an immobilizing agent such as C_{12}-C_{22} fatty alcohols and C_{12}-C_{22} fatty acids in amounts of from about 5% (by weight lotion formulation) to about 60% (by weight lotion formulation).

Significantly, Klofta, et al. fail to disclose that their lotion formulation includes from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent as required in claim 1. Further, Klofta, et al. fail to disclose that their lotion formulation includes an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmaric acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof as required in claim 1.

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[2] *Id.* at column 19, lines 23-26.
[3] *Id.* at column 17, lines 50-52.
[4] *Id.* at column 22, lines 51-55.

Recognizing that Klofta, et al. fail to make such a disclosure, the Office cites Krzysik, et al. and Bartels for combination with the Klofta, et al. reference. Specifically, the Office states that it would have been obvious to a person having ordinary skill in the art to combine the cited references as there would be an improved beneficial effect of a soft and lubricious feel and a better maintained skin barrier function, and further, deterioration of the tissue product carrying the lotion composition can be prevented. Furthermore, the Office states that it would have been obvious to combine the antioxidant used in Bartels with Klofta, et al. and Krzysik in order to achieve Applicants' claim 1.

Krzysik, et al. disclose a skin health enhancing soft wet wipe comprising an oil-in-water emulsion composition. The oil-in-water composition comprises a natural fat or oil, sterol or sterol derivative, humectant, emulsifying surfactant, and water. Specifically, in one exemplary embodiment, the oil-in-water composition comprises from about 0.1 to about 30 weight percent of natural fats or oils, from about 0.1 to about 10 weight percent of a sterol or sterol derivative, from about 0.1 to about 99.5 weight percent of an humectant, and from about 0.5 to about 20 weight percent of an emulsifying surfactant having an HLB range of about 7 to about 18, from about 45 to about 99.5 weight percent of water and the pH of the emulsion adjusted to a pH of about 4 to about 7.[5]

Bartels discloses a topical composition and method for treatment of the symptoms of diaper rashes and skin irritations

[5] U.S. 6,440,437 at column 3, lines 21-29.

caused by acidic secretions.[6] The topical composition comprises: a pH-raising ingredient; an anhydrous base ointment; polysorbate 80; a pharmaceutically acceptable diluent; and butylated hydroxyltoluene (BHT).[7] Embodiments of Bartels include a cream, dusting powder, spray, bath soak and effervescent tablet, and a bodyside diaper liner.[8]

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." The Court in KSR International further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would

[6] U.S. 2003/0157195 A1, at abstract.
[7] *Id.*
[8] *Id.*

have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as there is no apparent reason for one skilled in the art to modify and/or combine the references to arrive at each and every limitation of Applicants' claimed invention. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Specifically, the common sense of one ordinarily skilled in the art would not have provided a reason to combine the Klofta, et al. reference, the Krzysik reference and the Bartels reference to arrive at Applicants' composition of claim 1. As noted in M.P.E.P. § 2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references

can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests a reason for the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). While this test is not a rigid formula, it does provide helpful insight as it can be important to identify a reason that would have prompted a person of ordinary skill in the art to modify the elements as the new invention does.

A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the formulations of the Klofta, et al., Krzysik and Bartels references would not have been made.[9] More particularly, a close reading of the Krzysik reference actually teaches away from the combination of the Klofta, et al., Krzysik and Bartels references. As recognized by the Federal Circuit in *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994),[10] a reference teaches away "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out

[9] M.P.E.P. § 2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

in the reference, or would be led in a direction divergent from the path that was taken by the applicant."

Specifically, as disclosed in Klofta, et al., it is desirable for the lotion compositions to be **anhydrous** lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.[11] Moreover, Klofta, et al. explain that the "anhydrous nature of these lotions allows for more efficient dry transfer of the lotion to the skin. Intentional addition of water to the lotion would be **detrimental** to physical properties of the paper such as tensile and caliper. Water aids in the migration of the lotion throughout the web. This leads to fiber debonding and less lotion concentrated at the surface of the paper. This leads to both tensile and caliper losses; thus, it is beneficial to maintain an anhydrous lotion state as described herein."[12] Additionally, the composition in Bartels is also anhydrous.[13] Specifically, Bartels discloses an **anhydrous** base ointment that comprises up to 95% of the composition.[14]

As noted above, however, the Krzysik composition comprises from about 45% to about 99.5% by weight **water**. The water contained in the Krzysik composition may be a mixture of water and alcohol. The amount of alcohol in the water is up to about

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[10] Further upheld in the Board of Patent Appeals case Ex Parte Osborn and Comstock, Appeal No. 2007-1572.
[11] U.S. 6,238,682 at column 10, lines 51-57.
[12] *Id.* at column 10, lines 57-65.
[13] Bartels, at Abstract.
[14] *Id.* at [0020].

70 weight percent of the water and alcohol solution.[15] Even if alcohol is present in 70 weight percent of the water and alcohol solution, however, the compositions of Krzysik comprise at least about 13.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Krzysik reference, which are desirably incorporated into compositions having at least 13.5% by weight water with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water, and most preferably, less than 0.1% (by weight) water, and Bartels, which comprises up to 95% of an **anhydrous** base ointment. That is, one skilled in the art reading Klofta, et al. and Bartels would be "discouraged from following the path" of combining components of Krzysik's water-containing composition with their compositions.

Furthermore, a closer reading of Bartels teaches away from a combination with Klofta and Krzysik. More particularly, Krzysik focuses on a product that helps maintain skin barrier function in the diapered environment.[16] Bartels, conversely, specifically mentions that "the present invention does **not** purport or attempt to be a barrier cream (emphasis added),"[17] and the invention is looking for a "method besides barrier creams"[18] to treat diaper rashes. Thus, why would one having ordinary skill in the art interested in improving barrier function look to a reference that **specifically** mentions it does **not** have anything to do with barrier functions? Put another way, if

[15] U.S. 6,440,437 at column 3, lines 61-67.
[16] Krzysik, col. 2 line 64 – col. 3 line 5; col. 3 lines 45-47.
[17] Bartels, para. [0033].
[18] *Id.* at para. [0011].

Bartels is specifically looking for a different method as an alternative to barrier creams, why would one skilled in the art looking to improve barrier function be motivated to use the composition of Bartels? Applicants' respectfully assert that it would not have been obvious to one having ordinary skill in the art to look to Bartels for an antioxidant to use in barrier functions.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the Klofta, et al., Krzysik, and Bartels references. What is important is that there is no guidance provided by the cited references to arrive at such a specific combination.

Accordingly, there is simply no apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. Claim 1 is therefore patentable over the cited references.

Claims 2-14, 16-18 and 20-30 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

2. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1 and 23-24 under 35 U.S.C. 103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437), further in view of Bartels (U.S. Application No. 2003/0157195), and further in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 is discussed above.

Klofta, et al., Krzysik and Bartels are discussed above. Specifically, as discussed above, there is no reason to combine Klofta, et al., Krzysik and Bartels to arrive at each and every limitation of Applicants' claimed invention. Furthermore, as noted above, a close reading of the references would teach away from such a combination. Bowser, et al. fail to overcome the above shortcomings.

Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω-hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al., Krzysik, Bartels and Bowser, et al. references to arrive at Applicants' claim 1. Specifically, similar to the Krzysik reference discussed above, a close reading of the Bowser, et al. reference actually teaches

away from the combination of the Klofta, et al., Krzysik Bartels, and Bowser, et al. references.

Specifically, as noted above, it is desirable for the lotion compositions of Klofta, et al. and the compositions of Bartels to be anhydrous. Further, as noted above, Klofta, et al. explain that the intentional addition of water to the anhydrous lotion would be detrimental to physical properties of the paper such as tensile and caliper. The Bowser, et al. composition, however, can comprise from about 15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having at least 15% by weight water and, more preferably at least 50% by weight water, with the anhydrous compositions of Klofta, et al and Bartels. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

In the present Office Action, the Office states that "[n]either Klofta, Krzysik, nor Bowser suggest that a water content of 5-15% will adversely affect the functionality of petrolatum, mineral oil, antioxidants, sterols, or ceramide in a tissue product." Applicants respectfully disagree as Klofta specifically states that "[I]ntentional addition of water to the lotion would be detrimental to physical properties of the paper . . ."[19] The functionality, therefore, does indeed change when

[19] Klofta, col. 10, lines 57-61.

the water content is between 5%-15%, prompting Klofta to advise against any water content over 5%. MPEP § 2143.01 states that if the proposed modification "would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."[20] If Klofta, et al. were combined with Krzysik and/or Bowser, et al., the tissue paper of Klofta **would not** work for its intended purpose. Specifically, any water content above 5% in the lotion would decrease the surface concentration of the lotion ingredients, thereby decreasing the probability for more efficient dry skin transfer.[21] As such, there is no motivation or suggestion to combine Klofta, et al., Krzysik, Bartels and Bowser, et al. to arrive at Applicants' claim 1.

Furthermore, even if the addition of more than 5% water to the tissue paper did not change the functionality of the components already present on the tissue paper (which Applicants again assert is not the case), one skilled in the art still would have no reason to combine the cited references to arrive at Applicants' claim 1. Specifically, the Office states at pages 9-10 of the instant Office action that the use of the ingredients referred to in the tissue products of Krzysik and Bowser would have suggested to a person of ordinary skill in the art that they may be added to the tissue product of Klofta with beneficial effects because none of these references "suggest that a water content of 5-15% will adversely affect the

[20] MPEP § 2143.01(V), citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).
[21] Klofta, col. 11, lines 1-5.

functionality of petrolatum, mineral oil, antioxidants, sterols, or ceramide in a tissue product." Applicants submit that even if the Office was correct in stating that none of the cited references suggest that this water content would adversely affect the functionality of the other components (which Applicants again assert is not true), the Office is merely providing reasons why one skilled in the art would not be discouraged from making such a combination. The Office, however, has not pointed to any disclosure in any of the cited references that would actually motivate one skilled in the art to make such a combination. Applicants submit that the mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests a reason for the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). As the Office has pointed to no such reason in the cited references, Applicants submit that one skilled in the art would not and could not have been motivated to modify and/or combine the cited references. Accordingly, claim 1 is patentable over the cited references.

Claims 23-24 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

3. Double Patenting Rejections

Claims 1-14, 16-18, and 20-30 have been provisionally rejected under the judicially-created doctrine of obviousness-

type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,969 has not yet issued as a patent. Applicants will address the merits of this rejection, as appropriate, if the listed application issues as a patent before the application at hand.

In the instant Notice of Non-Compliant Amendment, the Office states that the Letter to Patent and Trademark Office filed on May 7, 2009 was not fully responsive as Applicants have not adequately replied to the Provisional Obviousness Type Double Patenting Rejection. Specifically, the Office states that a request to hold a rejection in abeyance is not a proper response to a rejection.

Applicants respectfully disagree. Applicants specifically assert that a terminal disclaimer is not necessary in the present application at this time. Specifically, as explained in MPEP §804, courts have sanctioned the practice of making Applicant aware of the **potential** double patenting problem **if** one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting; that is, there is not a problem unless and until one of the applications in the provisional double patenting rejection issues as a patent. Accordingly, Applicant need not file a terminal disclaimer until one of the applications issues as a patent. This is further explained in 35 U.S.C. § 111, which states that the "provisional" double patenting rejection

should continue to be made by the Examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

As neither of the applications has yet issued as a patent, a terminal disclaimer is not necessary. Instead, this rejection should be maintained as long as there are conflicting claims in more than one application and neither of the applications issue or unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-14, 16-18, and 20-30 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

/Christopher M. Goff/

Christopher M. Goff, Reg. No. 41,785
ARMSTRONG TEASDALE LLP
One Metropolitan Square, 26th Floor
St. Louis, Missouri 63102
314-621-5070

CMG/JMB/EMF/sb